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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/11/2003

124

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,572

Applicant(s)

KONDOROSI ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 8-29 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed December 20, 2002, paper no. 13, has been entered.

Claims 3-7 are cancelled.

Claims 12-29 are newly added.

Claims 1-2 and 8-29 are pending. Claims 1-2 and 8-11 are withdrawn from consideration as being directed to nonelected inventions. Claims 12-29 are examined on the merits in the instant office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Information Disclosure Statement

The information disclosure statement filed December 20, 2002 fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e) or the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

Specification

The disclosure remains objected to because of the following informalities: the specification does not contain a brief description of the drawings section (MPEP § 608.01(f) and 37 CFR 1.74). Applicant is reminded that no new matter may be added. Appropriate correction is required.

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Claim Objections

Claim 12(b) is objected to because of the following informalities: the plural "plants" is recited where it is apparent that the singular "plant" was intended. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 29 recites the limitation "a consensus sequence ($X_1YNX_2LLX_3NNX_4FG$) and where $X_1 = A$ or S , $X_2 = T$ or R , $X_3 = R$ or K , and $X_4 = L$ or M ". This limitation is not supported by the specification and thus constitutes new matter.

Claims 12-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth for claims 3-7 in the office action mailed June 20, 2002.

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Applicant's arguments filed December 20, 2002, have been fully considered but they are not persuasive.

Applicant argues that the cancellation of claims 3-7 renders the rejection moot.

The Office maintains that the newly submitted claims are also directed to a genus of sequences that are not adequately described. The newly submitted claims are drawn to an isolated nucleic acid comprising SEQ ID NO:1 or any fragment thereof that encodes a polypeptide that comprises WD-40 repeats and that regulates any aspect of plant differentiation and/or endoreduplication, nucleic acid sequences that hybridize to SEQ ID NO:1 under any stringency conditions, nucleic acid sequences encoding a protein that is at least 70% similar to the CCS52Ms protein, nucleic acid sequences encoding the CCS52Ms protein, nucleic acid sequences encoding a polypeptide of SEQ ID NO:2 or any fragment thereof that regulates any aspect of plant differentiation and endoreduplication, and nucleic acid sequences encoding a protein that is at least 70% similar to SEQ ID NO:2 that regulates any aspect of plant differentiation and endoreduplication and that comprises repeated WD-40 motifs and a consensus sequence (X₁YNX₂LLX₃NNX₄FG). However, the specification describes only a single purified nucleic acid fragment (ccs52Ms) obtained from *Medicago sativa*, SEQ ID NO:1, that encodes a polypeptide of SEQ ID NO:2 (CCS52Ms), which has homology to the fizzy-related class of proteins (page 3), which inhibits growth and induces endoreduplication expressed in *S. pombe* SP-Q01, which reduces CDC13 when expressed in *S. pombe* SY1 (pages 14-16), and which increases the conversion of calli to embryos in transgenic *Medicago truncatula* (pages 20-21). This does not constitute a substantial portion of the claimed genus, which encompasses a multitude of different nucleotide sequences and plant proteins, including those yet to be

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discovered. The disclosure of a single nucleotide sequence that encodes a plant protein that comprises WD-40 repeats and that increases the conversion of calli to embryos does not provide an adequate description of the claimed genus, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

Claims 12-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising SEQ ID NO:1 that encodes a polypeptide of SEQ ID NO:2 that inhibits growth and induces endoreduplication in *S. pombe*, and that increases the conversion of calli to embryos in *Medicago truncatula*, does not reasonably provide enablement for other nucleic acid sequences or fragments thereof, encoding other polypeptides or fragments thereof, that regulate any aspect of plant differentiation and/or endoreduplication in any cell type. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to an isolated nucleic acid comprising SEQ ID NO:1 or any fragment thereof that encodes a polypeptide that comprises WD-40 repeats and that regulates any aspect of plant differentiation and/or endoreduplication. The claims are also drawn to nucleic acid sequences that hybridize to SEQ ID NO:1 under any stringency conditions, nucleic acid sequences encoding a protein that is at least 70% similar to the CCS52Ms protein, nucleic acid sequences encoding the CCS52Ms protein, nucleic acid sequences encoding a polypeptide of

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SEQ ID NO:2 or any fragment thereof that regulates any aspect of plant differentiation and endoreduplication, and nucleic acid sequences encoding a protein that is at least 70% similar to SEQ ID NO:2 that regulates any aspect of plant differentiation and endoreduplication and that comprises repeated WD-40 motifs and a consensus sequence (X₁YNX₂LLX₃NNX₄FG).

Additionally, the claims are drawn to vectors, host cells and plant cells, as well as a transgenic plant, comprising said nucleic acid sequences.

The specification discloses a single isolated nucleic acid (ccs52Ms) obtained from *Medicago sativa*, set forth in SEQ ID NO:1, that encodes a polypeptide of SEQ ID NO:2 (CCS52Ms), which has homology to the fizzy-related class of proteins (page 3), which inhibits growth and induces endoreduplication when expressed in *S. pombe* SP-Q01, which reduces CDC13 when expressed in *S. pombe* SY1 (pages 14-16), and which increases the conversion of calli to embryos in transgenic *Medicago truncatula* (pages 20-21). The specification does not disclose other effects of SEQ ID NO:2 on other aspects of plant differentiation, or the effect of SEQ ID NO:2 on endoreduplication in plant cells. The specification does not disclose the structure of any fragments of SEQ ID NO:1 that encode a polypeptide that comprises WD-40 repeats and that regulates plant differentiation and/or endoreduplication. The specification does not disclose the structure of any nucleic acid sequences that hybridize to SEQ ID NO:1 and that encode a polypeptide that comprises WD-40 repeats and that regulates plant differentiation and/or endoreduplication. The specification does not disclose the structure of any nucleic acid sequences encoding a protein that is at least 70% similar to the CCS52Ms protein or that encodes a CCS52Ms protein other than SEQ ID NO:2. The specification does not disclose the structure of any fragments of SEQ ID NO:2 that encode a polypeptide that comprises WD-40 repeats and

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that regulates plant differentiation and/or endoreduplication. The specification does not disclose the structure of any nucleic acid sequence encoding a protein that is at least 70% similar to SEQ ID NO:2 that regulates any aspect of plant differentiation and endoreduplication and that comprises repeated WD-40 motifs and a consensus sequence (X₁YNX₂LLX₃NNX₄FG).

While one of skill in the art could readily make fragments of SEQ ID NO:1, sequences that hybridize to SEQ ID NO:1, fragments of SEQ ID NO:2 or sequences encoding a protein that is at least 70% similar to SEQ ID NO:2, it would require undue experimentation to determine on the basis of nucleotide or amino acid sequence which of these sequences encode a polypeptide that regulates plant differentiation and/or endoreduplication, as the specification provides no guidance with respect to which nucleotides or amino acids must be retained by sequences that encode a functional polypeptide. The specification also lacks guidance with respect to whether any amino acid sequence other than SEQ ID NO:2 would constitute a CCS52Ms protein, and if so, what amino acids of SEQ ID NO:2 would be retained by another CCS52Ms protein. Furthermore, while one of skill in the art could readily express SEQ ID NO:1 or a nucleic acid encoding SEQ ID NO:2 in a transgenic plant cell or plant, it would require undue experimentation to determine how to express these nucleic acids in a way that would regulate aspects of plant differentiation other than the conversion of calli to embryos, because the ability of a nucleic acid to alter the phenotype of a transgenic plant is unpredictable, and because the specification does not teach how to express these nucleic acids in a way that regulates other aspects of plant differentiation, such as root differentiation, shoot differentiation, floral differentiation, etc. Additionally, while Applicant has shown that expression of SEQ ID NO:1 in yeast induces endoreduplication, Applicant has not shown a similar effect in plants. It would

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require undue experimentation to determine how to express SEQ ID NO:1 in plants in a way that would regulate endoreduplication, because it is unpredictable whether expression of a nucleic acid will have the same effect in homologous versus heterologous systems.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 parts (a)-(c) and claim 29 parts (a)-(b), and claims dependent thereon, are indefinite in the recitation of "regulates". It is unclear in what way the polypeptide "regulates" differentiation or endoreduplication, as a process may be regulated in more than one way. Does the polypeptide increase the amount of differentiation or endoreduplication? Does the polypeptide increase the rate of differentiation or endoreduplication? Does the polypeptide decrease the amount of differentiation or endoreduplication? Does the polypeptide decrease the rate of differentiation or endoreduplication? Does the polypeptide direct the location of differentiation or endoreduplication?

Claim 12 parts (a)-(c) and claim 29 parts (a)-(b), and claims dependent thereon, are indefinite in the recitation of "differentiation". It is unclear what aspects of "differentiation" are regulated by the polypeptide, as differentiation encompasses many different aspects of plant development. Is the differentiation of the root regulated by the polypeptide? Is the differentiation

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of the shoot regulated by the polypeptide? Is the differentiation of the flower regulated by the polypeptide? Is the differentiation of the fruit regulated by the polypeptide?

Claim 12 part (b) and claims 14-15, and claims dependent thereon, are indefinite in the recitation of "stringent conditions". It is unclear what conditions would yield the claimed nucleic acid, as those skilled in the art define stringent conditions differently. It is suggested that the claims be amended to recite specific hybridization conditions.

Claim 12 is indefinite in the recitation of "wherein stringent conditions comprise washing in 2X SSC at 65°C" after part (c). It is unclear whether this phrase is meant to limit only part (c) of claim 12, or whether this phrase is meant to limit parts (b) and (c) of claim 12.

Claim 12 is indefinite in the use of a comma between subparts (a), (b) and (c). It is unclear whether the claimed nucleic acid comprises (a), (b) and (c), or whether the claimed nucleic acid comprises (a), (b) or (c).

Claims 16-19 are indefinite in the recitation of the acronym "CCS52Ms", as an acronym may be associated with more than one meaning. It is also unclear what sequence(s) are encompassed by "CCS52Ms protein".

Claims 16, 18 and 29 are indefinite in the recitation of "% similar". It is unclear what type of similarity is intended - by sequence identity, function, evolutionary homology?

Claim 29 is indefinite in the use of a comma between subparts (a) and (b). It is unclear whether the claimed nucleic acid encodes a polypeptide consisting of (a) and (b), or whether the claimed nucleic acid encodes a polypeptide consisting of (a) or (b).

Claim 29 is indefinite in the use of parentheses. It is unclear whether the sequence enclosed with the parentheses is meant to limit "a consensus sequence".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-23 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al. (Mol. Gen. Genet. Vol. 257, No. 4, pages 387-391, February 1998), for the reasons of record set forth for claims 3-7 in the office action mailed June 20, 2002.

Applicant's arguments filed December 20, 2002, have been fully considered but they are not persuasive.

Applicant argues that the rejection is moot in view of the cancellation of claims 3-7, and that Zhou et al. would not anticipate claims 12-29 because Zhou does not describe a nucleic acid of SEQ ID NO:1, or fragments of SEQ ID NO:1, or nucleic acids that cross hybridize to SEQ ID NO:1 that encode proteins that regulate plant differentiation or endoreduplication (reply page 6).

The Office maintains that Zhou et al. anticipates the rejected claims for the following reasons. First, the rejected claims are not limited to a nucleic acid of SEQ ID NO:1. Second, the rejected claims do not limit the size or structure of the fragments of SEQ ID NO:1, such that the rejected claims read on a nucleic acid sequence comprising a fragment of SEQ ID NO:1 that is as small as a single nucleotide. Third, the rejected claims do not recite specific hybridization conditions, such that the rejected claims read on a nucleic acid sequence that would hybridize to SEQ ID NO:1 under any hybridization conditions. Fourth, the rejected claims are indefinite in the recitation of "CCS52Ms" protein, as discussed *supra* under 35 USC 112, second paragraph,

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such that the rejected claims are not limited by "CCS52Ms". Fifth, the rejected claims do not recite what type of plant differentiation is regulated or how the polypeptide effects such regulation, such that the rejected claims read on any nucleic acid encoding a polypeptide that regulates any aspect of plant differentiation in any way. The nucleic acid taught by Zhou et al. encodes a polypeptide that regulates plant differentiation because it encodes a polypeptide that regulates photomorphogenesis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al. (Mol. Gen. Genet. Vol. 257, No. 4, pages 387-391, February 1998) in view of Applicant's admitted prior art.

The claims are drawn to the vector of claim 22 wherein said promoter is an inducible or tissue specific promoter.

The teachings of Zhou et al. are discussed *supra*.

Zhou et al. do not teach an inducible or tissue specific promoter.

Applicant teaches that inducible and tissue specific promoters were known and used in the art at the time of Applicant's invention (page 9 line 33 to page 10 line 17).

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Given the success of Zhou et al. in making and using a vector comprising a nucleic acid comprising a fragment of SEQ ID NO:1 operably linked to a constitutive promoter, and given that inducible and tissue specific promoters were known and used in the art at the time of Applicant's invention, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to make and use a vector comprising a nucleic acid comprising a fragment of SEQ ID NO:1 operably linked to an inducible or tissue specific promoter, without any surprising or unexpected results, as the use of an inducible or tissue specific promoter would be an obvious variation of design parameters. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
March 10, 2003

Amy Nelson
for
Phuong Bui

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
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